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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,078	04/08/2004	Robert A. Davis	56630US007	1677

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EXAMINER
HAND, MELANIE JO

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
08/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/821,078

Applicant(s)

DAVIS ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/23/07, 7/9/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed May 23, 2007 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding the rejection of the claims under 35 U.S.C. 102: Applicant argues that the Office cites no technical reference to support the argument that any material impervious to water will also be impervious to ethylene oxide. This argument is supported by the widely understood fact that one gaseous ethylene oxide molecule is larger than a gaseous or liquid water molecule. Thus, if a gaseous water molecule cannot permeate, the ethylene oxide molecule certainly cannot not permeate either. Again, applicant has not set forth an example of a water permeable material (permeable to water either of, or both, liquid or vapor form) that is simultaneously impermeable to ethylene oxide as this would constitute proper evidence that a material's permeability to water is not an indicator of permeability to ethylene oxide. It is true that a material being water permeable is not necessarily a testament to its ethylene oxide water vapor-permeability or lack thereof, however it is assured that a material which is impervious to the vapor form of water (as was stated with reference to the barrier layers taught by Dischler in the rejection of claim 58) will be impervious to ethylene oxide vapor as well. Applicant's argument regarding various other materials taught by Dischler that may or may not be impermeable to ethylene oxide is irrelevant. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft

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Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998)

As to applicant's argument that Dischler does not recognize a problem solved by the claimed invention, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a vent opening that allows for simultaneous flow of liquid out of the container and air into the container through separate openings) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant merely claims a vent orifice, not separate openings or orifices.

Applicants' arguments with regard to dependent claim 61 have been fully considered but are not persuasive as Applicants' arguments depend entirely on Applicants' arguments regarding the rejection of claim 58, which have been addressed *supra*.

Information Disclosure Statements

The information disclosure statements (IDSs) filed May 23, 2007 and July 9, 2007 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the information disclosure statements do not contain either of the required statements as set forth in 37 C.F.R. 1.97(e)(1) and (e)(2). The IDSs have been placed in the application file, but the information

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referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in these information disclosure statements or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Double Patenting

The provisional double patenting rejection made in the Office action mailed June 12, 2006 has been withdrawn in view of the cancellation of claims 58 and 61-66. However a new double patenting rejection is made herein in view of an amendment to the copending application No. 10/263518, which has been allowed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-16 and 62 of copending Application No.

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10/263,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are a broader recitation of the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 58-60 and 62-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Dischler (U.S. Patent No. 6,585,693).

With respect to **Claims 58,64-67,69,70,73,74**: Dischler teaches a single-dose syringe 24 comprising cylindrical syringe body 62 (container) defining an interior volume, wherein said container is comprised of at least one polymeric layer (wall) that does not contain metal lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor

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forms of said antiseptic. Dischler teaches polymers for the lamina, all of which are substantially water-impermeable (liquid and vapor) and thus will also be impermeable to gaseous ethylene oxide, as an ethylene oxide molecule is larger than a water molecule.

With respect to **Claim 59**: Dischler teaches a syringe body 62 having walls comprised of polymeric lamina and therefore teaches that the barrier covers 100% (i.e. at least 60%) (claim 60) of the walls of body 62. Applicant has not established sufficient criticality for having a barrier material that covers less than 100%, therefore this limitation is considered an optimization of the surface area of said barrier layer(s). It would be obvious to one of ordinary skill in the art to modify the barrier coverage area to be less than 100% as the blister chambers collectively are not coextensive with said walls and therefore would only need the barrier functionality in the areas adjacent said chambers. Leaving the remainder free of barrier material would facilitate transparency and visual inspection of said syringe.

With respect to **Claim 62**: Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

With respect to **Claims 63,72,75**: Dischler teaches polyvinylidene chloride (halogenated polyolefin).

With respect to **Claim 68**: Dischler teaches that the barrier lamina are flexible.

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With respect to **Claim 71**: Dischler teaches that the polymer lamina are attached to one another via additional heat sealable polymer (heat activated adhesive) lamina therebetween that function also as barrier lamina.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 76 and 77 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dischler.

With respect to **claim 76**: The device of Dischler meets substantially all of the claim limitations of claim 76. Dischler is silent regarding the percent of weight lost by the container based upon the weight of the skin composition. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, a dispenser according to claim 73) except for a property or function (in the present case, percent of weight lost by the container based upon the weight of the skin composition when placed in a convection oven at 60 degrees Celsius for 14 days) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

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With respect to **claim 77**: The device of Dischler meets substantially all of the claim limitations of claim 76. Dischler is silent regarding a permeability to gaseous ethylene oxide. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, in this case, a dispenser according to claim 73) except for a property or function (in the present case, a permeability to gaseous ethylene oxide of 20 mg.hr/cm² or less) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). The limitation "when determined in accordance with the Gaseous Ethylene Oxide Permeability Test" is given little patentable weight herein.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dischler (693).

With respect to **Claims 61,79-81**: Dischler does not explicitly teach any of the items set forth in claim 61, but does teach that second chamber 42 contains an injection prep or other sterilizing fluid, of which povidone (iodine complex) and chlorhexidine digluconate are examples that are well-known in the art, therefore it would be obvious to one of ordinary skill in the art to fill second chamber 42 with povidone with a reasonable expectation of success.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dischler in view of Jampani et al (U.S. Patent Application Publication No. 2002/0022660).

With respect to **claim 78**: Dischler does not teach that the iodine complex comprises an iodophor. Jampani teaches that iodophors are commonly known antiseptics, therefore it would be obvious to one of ordinary skill in the art to modify the device of Dischler such that the iodine complex is an iodophor as taught by Jampani with a reasonable expectation of success. ('660, ¶¶0007)

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

August 1, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'T. Zalukaeva', is written over the printed name and title.